SM.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/068,067	02/05/2002	Marc E. Rothenberg	CMC/153	7530

26875 7590 06/18/2004

WOOD, HERRON & EVANS, LLP
2700 CAREW TOWER
441 VINE STREET
CINCINNATI, OH 45202

EXAMINER	
ASHEN, JON BENJAMIN	
ART UNIT	**PAPER NUMBER**
1635	

DATE MAILED: 06/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/068,067	ROTHENBERG ET AL.	
	Examiner	Art Unit	
	Jon B. Ashen	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-46* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-8 and 42-45 are drawn to an isolated CCR3 regulatory site comprising exon 1 of a human CCR3 gene, classified in class 536, subclass 24.1.

II. Claims 19-20 and 40 are drawn to an isolated CCR3 regulatory site comprising exon 2 of a human CCR3 gene classified in class 536, subclass 24.1.

III. Claims 25-26 and 41 are drawn to an isolated CCR3 regulatory site comprising exon 3 of a human CCR3 gene classified in class 536, subclass 24.1.

VI. Claims 31-34 are drawn to an isolated CCR3 regulatory site comprising a promoter of a human CCR3 gene, classified in class 536, subclass 24.1.

V. Claims 10-18 and 46 are drawn to a method for cell selective gene expression in a human by providing a pharmaceutically acceptable

formulation of at least one regulatory element capable of binding to an untranslated exon wherein said element regulates transcription of exon 1 in a human cell containing a CCR3 gene or mRNA, classified in class 514, subclass 44.

VI. Claims 10-14, 21-24 and 46 are drawn to a method for cell selective gene expression in a human by providing a pharmaceutically acceptable formulation of at least one regulatory element capable of binding to an untranslated exon wherein said element regulates transcription of exon 2 in a human cell containing a CCR3 gene or mRNA, classified in class 514, subclass 44.

VII. Claims 10-14, 27-30 and 46 are drawn to a method for cell selective gene expression in a human by providing a pharmaceutically acceptable formulation of at least one regulatory element capable of binding to an untranslated exon wherein said element regulates transcription of exon 3 in a human cell containing a CCR3 gene or mRNA, classified in class 514, subclass 44.

VIII. Claims 36-39 are drawn to a method for cell selective gene expression in a human comprising providing at least one regulatory element for binding to a promoter in a human cell containing a CCR3 gene or mRNA wherein

said element regulates transcription of exon 1, classified in class 514, subclass 44.

IX. Claims 36-39 are drawn to a method for cell selective gene expression in a human comprising providing at least one regulatory element for binding to a promoter in a human cell containing a CCR3 gene or mRNA wherein said element regulates transcription of exon 2, classified in class 514, subclass 44.

X. Claims 36-39 are drawn to a method for cell selective gene expression in a human comprising providing at least one regulatory element for binding to a promoter in a human cell containing a CCR3 gene or mRNA wherein said element regulates transcription of exon 3, classified in class 514, subclass 44.

XI. Claims 36-39 are drawn to a method for cell selective gene expression in a human comprising providing at least one regulatory element for binding to a promoter in a human cell containing a CCR3 gene or mRNA wherein said element regulates transcription of exon 4, classified in class 514, subclass 44.

2. Claim 9 link(s) the inventions groups V-VII. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 9. Claim 35 link(s) the inventions of groups VIII-XI. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 35. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Claims 10-14 and 46 are generic to groups V-VI. Claims 36-39 are generic to groups VIII-XI. These claims will be examined limited to the groups elected. The inventions are distinct, each from the other because of the following reasons:

3. Inventions in groups I-IV and groups V-XI are related as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with

another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). The inventions of groups I-IV are drawn to isolated regulatory sites of a human CCR3 gene. The inventions of groups V-XI are drawn to methods of regulating gene expression by binding of regulatory elements to a) untranslated CCR3 exons (groups V-VII) or b) a promoter in a human cell containing a CCR3 gene or mRNA. In the instant case, the inventions of group I-IV can all be used in a materially different process; i.e., hybridization assays for the detection of cell specific gene expression. Therefore, the inventions of groups I-IV are distinct from the inventions of groups V-XI.

4. Inventions of groups I-III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The invention of group I is drawn to an isolated CCR3 regulatory site comprising exon 1 of a human CCR3 gene. The invention of group II is drawn to an isolated CCR3 regulatory site comprising exon 2 of a human CCR3 gene. The invention of group III is drawn to an isolated CCR3 regulatory site comprising exon 3 of a human CCR3 gene. In the instant case the different inventions are not disclosed as capable of use together and will have different functions. The function of the invention of group I is to regulate the transcription of exon I, the function of the invention of group II is to regulate the transcription of exon 2 and the function of the invention of group III is

to regulate the transcription of exon 3. Therefore, the inventions of groups I-III are unrelated.

5. Inventions of groups I-III and group IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The inventions of groups I-III are described above. The invention of group IV is drawn to an isolated CCR3 regulatory site comprising a promoter of a human CCR3 gene. In the instant case the different inventions are not disclosed as capable of use together and will have different functions. The invention of group IV functions to enhance gene expression of the human CCR3 gene. The inventions of group I-III function to regulate the transcription of particular exons that comprise parts of the human CCR3 gene. Therefore, the inventions of groups I-III and IV are unrelated.

6. Inventions of groups V-VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The invention of group V is drawn to a method for cell selective gene expression in a human by providing a pharmaceutically acceptable formulation of at least one regulatory element capable of binding to and regulating the transcription of exon 1 in a human cell containing a CCR3 gene or mRNA. The invention of group VI is drawn to a method for cell selective gene expression in a human by providing a

pharmaceutically acceptable formulation of at least one regulatory element capable of binding to and regulating the transcription of exon 2 in a human cell containing a CCR3 gene or mRNA. The invention of group VII is drawn to a method for cell selective gene expression in a human by providing a pharmaceutically acceptable formulation of at least one regulatory element capable of binding to and regulating transcription of exon 3 in a human cell containing a CCR3 gene or mRNA. In the instant case the different inventions are not disclosed as capable of use together and will have different functions. The function of the invention of group V is transcriptional regulation of exon 1, the function of the invention of group VI is transcriptional regulation of exon 2 and the function of the invention of group VII is the transcriptional regulation of exon 3. Therefore, the inventions of groups V-VII are unrelated.

7. Inventions of groups V-VII and groups VIII-XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The inventions of groups V-VII are described above. The inventions of group VIII-XI are drawn to methods for cell selective gene expression in a human comprising providing at least one regulatory element for binding to a promoter in a human cell containing a CCR3 gene or mRNA wherein said element regulates transcription of at least one of exon 1 (group VIII), exon 2 (group IX), exon 3 (group X) and exon 4 (group XI). In the instant case the different inventions are not disclosed as capable of use together and will have different functions. The inventions of groups V-VI

will function to provide a regulatory element capable of binding an untranslated exon sequence, thereby regulating the transcription of exons 1 through 3 respectively, of a cell containing a human CCR3 gene. The inventions of groups VIII-XI will function to provide a regulatory element capable of binding a promoter thereby regulating the transcription of exons 1 through 4 respectively, in a human cell containing a CCR3 gene or mRNA. Therefore, the inventions of groups V-VII and VIII-XI are unrelated.

8. Inventions of groups VIII-XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The inventions of groups VIII-XI are drawn to methods for cell selective gene expression in a human comprising providing at least one regulatory element for binding to a promoter in a human cell containing a CCR3 gene or mRNA wherein said element regulates transcription of exons 1-4 respectively. In the instant case the different inventions are not disclosed as capable of use together and will have different functions. The invention of group VIII functions to provide a regulatory element that binds a promoter in a human cell containing a CCR3 gene or mRNA wherein said element regulates transcription of exon 1. The invention of group IX functions to provide a regulatory element that binds a promoter in a human cell containing a CCR3 gene or mRNA wherein said element regulates transcription of exon 2 etc... Therefore, the inventions of groups VIII-XI are unrelated.

9. Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification and would require divergent searches of literature databases placing an undue administrative burden on the examiner, restriction for examination purposes as indicated is proper.

10. A telephone call was made to Beverly Lyman Ph.D. on 6/17/04 to request an oral election to the above restriction requirement, but did not result in an election being made.

11. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon B. Ashen whose telephone number is 571-272-2913. The examiner can normally be reached on Monday - Friday, 7:30 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on 517-272-0670. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jba

SEAN McGARRY
PRIMARY EXAMINER
1635